IN THE CLAIMS

1. (Previously Presented) A method for solubilizing and recovering, in bioactive form, a target polypeptide from a host organism in which the target polypeptide is present in insoluble form, which comprises:

disrupting the host cell to produce a lysate;

recovering lysate precipitate containing the target polypeptide;

solubilizing the lysate precipitate in a denaturant-free, non-buffered solubilization solution producing a solubilization preparation that comprises 1) a concentration of sodium hydroxide about 8 and about 10 mM and 2) a concentration of polypeptide about 1 and about 4mg polypeptide per ml solubilization solution, wherein the resultant solubization preparation has a pH of about 9 and about 11.2.

2. (Previously Presented) The method of claim 1, wherein the solubilization solution is free of denaturants and detergents.

3. (Previously Presented) The method of claim 1, further comprising the step of purifying the bioactive target polypeptide.

4. (Previously Presented) The method of claim 1, where the solubilization preparation has a pH about 10.5 to about 11.2

5. (Previously Presented) The method of claim 1, wherein the solubilization preparation comprises sodium hydroxide about 8.0 to about 10 mM.

6. (Previously Presented) The method of claim 1, wherein the solubilization preparation comprises a concentration of polypeptide about 1.0 to about 4 mg polypeptide per ml of solubilization solution.

7. (Original) The method of claim 1, wherein the solubilization solution further comprises a stabilizing compound.

8. (Previously Presented) The method of claim 7, wherein the stabilizing compound is at concentration between about 1 to about 20 mM.

9. (Original) The method of claim 7, wherein the solubilization solution further comprises a second stabilizing compound.

10. (Original) The method of claim 7, wherein the stabilizing compound is a stabilizing sugar, stabilizing polyol, stabilizing amino acid or stabilizing polymer.

11. (Previously Presented) The method of claim 10, wherein the stabilizing polyol is mannitol and the stabilizing sugar is lactose.

12. (Original) The method of claim 7, wherein the host organism is bacteria or yeast.

13. (Previously Presented) The method of claim 1, wherein the host is an Escherichia coli cell.

14. (Previously Presented) The method of claim 13, wherein the host cell is a Yeast cell.

15. (Original) The method of claim 1, wherein the target polypeptide is present within the host organism in inclusion bodies

16. (Previously Presented) The method of claim 1, wherein the target polypeptide is a protein or a subunit of the protein.

17. (Previously Presented) The method of claim 1 wherein said target polypeptide is a protein.

18. (Previously Presented) The method of claim 1 wherein said target polypeptide is troponin.

19. (Previously Presented) The method of claim 1 wherein said target polypeptide is troponin I.

20. (Canceled)

21. (Canceled)

22. (Currently Amended) A method for formulating a target bioactive polypeptide into a pharmaceutically acceptable form , comprising dialyzing or ultrafiltering-diafiltering the target biotactive polypeptide into an aqueous stabilization buffer containing a buffering salt and stabilizing compounds ~~The method of claim 20~~, wherein the stabilization buffer ~~solution~~ contains a buffer salt at concentration about 5 to 40 mM.

23. (Currently Amended) A method for formulating a target bioactive polypeptide into a pharmaceutically acceptable form , comprising dialyzing or ultrafiltering-diafiltering the target biotactive polypeptide into an aqueous stabilization buffer containing a buffering salt and stabilizing compounds ~~The method of claim 20~~, wherein the stabilizing compound ~~in the formulation solution~~ is a sugar or polyol

24. (Currently Amended) The method of claim ~~20~~ 23, wherein ~~the~~ a stabilizing compound of said stabilizing compounds ~~compound in the formulation solution~~ is a sugar at concentration about 2 to about 12 mM.

25. (Currently Amended) The method of claim ~~20~~ 23, wherein ~~the~~ a stabilizing compound of said stabilizing compounds ~~compound in the formulation solution~~ is a polyol at concentration about 5 to about 100 mM.

26. (Previously Presented) A method for solubilizing and recovering, in bioactive and isolated form a target polypeptide from a host organism in which the target polypeptide is present in insoluble form, which comprises:

(a) disrupting the host cell to produce a lysate;

(b) recovering a precipitate containing the target polypeptide from the lysate;

(c) solubilizing the precipitate in a denaturant-free non-buffered solubilization solution to produce a solubilization preparation that comprises

1) hydrogen chloride between 10 and 20 mM; and

2) bioactive target polypeptide between 1 and 4 mg per ml solubilization solution, and

3) pH between 2.0 and 3.0.

27. (Original) The method of claim 26, further comprising adjusting the pH of the supernatant to pH 9.5 with NaOH.

28. (Previously Presented) The method of claim 26, wherein the solubilization solution is free of denaturants and detergents.

29. (Previously Presented) The method of claim 26, wherein the solubilization preparation has a pH about 2.2 to about 2.8.

30. (Previously Presented) The method of claim 26, wherein the solubilization preparation comprises a concentration of hydrogen chloride about 10 to about 20 mM.

31. (Previously Presented) The method of claim 26, wherein the solubilization preparation comprises a concentration of polypeptide about 2.5 to about 3 mg polypeptide per ml solubilization solution.

32. (Previously Presented) The method of claim 26, wherein the solubilization preparation comprises a concentration of polypeptide about 1.8 to about 2 mg polypeptide per ml solubilization solution.

33. (Original) The method of claim 26, wherein the solubilization solution further comprises a stabilizing compound.

34. (Previously Presented) The method of claim 33, wherein the stabilizing compound is at concentration about 1 to about 20 mM.

35. (Original) The method of claim 33, wherein the solubilization solution further comprises a second stabilizing compound.

36. (Original) The method of claim 33, wherein the stabilizing compound is a sugar, polyol, amino acid or polymer.

37. (Original) The method of claim 33, wherein the stabilizing compound is mannitol and lactose.

38. (Original) The method of claim 26, wherein the host cell is bacteria or yeast.

39. (Previously Presented) The method of claim 38, wherein the host cell is an Escherichia coli cell.

40. (Original) The method of claim 38, wherein the host cell is a Saccharomyces cell.

41. (Original) The method of claim 38, wherein the heterologous polypeptide is present within inclusion bodies within the host cell.

42. (Previously Presented) A method for isolating recombinant polypeptides comprising:

providing a non-buffered solution containing a stabilizing compound and hydrogen chloride between 10 and 20 mM;

producing a polypeptide solution about 1 to about 4 mg polypeptide per ml by adding to the non-buffered denaturant free solution an insoluble recombinant polypeptide, wherein the polypeptide solution has a pH about 2.0 to about 3.0;

increasing the pH of the polypeptide solution to between about 4 and 5 using 1N NaOH;

centrifuging the polypeptide solution and recovering precipitate-free supernatant; ~~and~~

adjusting the pH of the supernatant to about pH 9 to about 10.5 with 1N NaOH; and retaining the supernatant comprising isolated target polypeptide.

43. (Previously Presented) A method for isolating recombinant polypeptides comprising:

providing a non-buffered solution containing a stabilizing compound and sodium hydroxide about 8 to about 10 mM;

producing a polypeptide solution about 1 to about 4 mg polypeptide per ml by adding to the non-buffered denaturant free solution an insoluble recombinant polypeptide, wherein the polypeptide solution has a pH about 9 to about 11.2;

lowering the pH of the polypeptide solution to about 4 to 5 using 1N NaOH;

centrifuging the polypeptide solution and recovering precipitate-free supernatant;

adjusting the pH of the supernatant to pH of about 9 to about 10.5 with 1N NaOH; and

retaining the supernatant comprising isolated target polypeptide, at least about 10% more pure than the isolated target polypeptide in insoluble form.

44. (Previously Presented) A method for preparing bioactive recombinant polypeptide that has been denatured in a chaotrope-containing solution, comprising:

decreasing the concentration of the chaotropic agent in the chaotrope-containing solution by dialyzing the chaotrope-containing solution against a renaturing buffer of pH of about 9 to about 10.5 and buffer concentration of about 10 to about 50 mM, wherein the renaturing buffer further contains a stabilizing compound.

45. (Original) The method of claim 44, wherein the stabilizing compound is a sugar or polyol.

46. (Previously Presented) The method of claim 44, wherein the stabilizing compound is a sugar about 2 to about 12 mM.

47. (Previously Presented) The method of claim 44, wherein the stabilizing compound is a polyol about 5 to about 100 mM.